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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,597	04/30/2001	Antoni P. Tomsia	IB-1627	3236

8076 7590 05/22/2002

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EXAMINER

SPERTY, ARDEN B

ART UNIT	PAPER NUMBER
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1775

5

DATE MAILED: 05/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

MF-15

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/845,597	TOMSIA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Arden B. Sperty	1775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 April 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. A second request from applicant for a corrected filing receipt erroneously claims benefit to 60/204,556. The correct application is 60/201,556, per a filing receipt dated August 25, 2000. Therefore the correct priority date is May 1, 2000, benefit of 60/201,556.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 3, 5-6, 9-10, 13-17 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite because they require a glass/hydroxyapatite admixture (claim 1, line 4), but also do not require hydroxyapatite (claim 1, line 11). Must the hydroxyapatite be present?

4. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble of claim 1 is misleading because it is drawn to a multilayer article while the body of the claim is drawn to an article with only one layer, a "first layer", and no further layers.

5. Claims 7 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what glass compositions are referred to by the phrase, "two

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or more glasses chosen from the glass composition of claim 1 (or 20).” Claims 1 and 20 each appear to only contain one glass composition.

6. Claims 12 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. How can a composition be comprised of both 100 wt% glass and 40 wt% hydroxyapatite (claim 12, line 8; claim 19, last line)? It appears that the sum of the components should equal 100%, therefore it is unclear what wt%’s of glass and hydroxyapatite are required.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,077,132 to Maruno in view of USPN 5,562,733 to Weissbach.

USPN 5,077,132 to Maruno teaches a multilayer article comprising a Ti or Ti<sub>6</sub>Al<sub>4</sub>V metal substrate (col 6, line 14), a first layer comprising an inner and outer surface, said first layer comprising a glass composition with HA particles therein, wherein said HA particles are present in the glass composition in the amount of 0-50 wt% (col 8, lines 51-64). Maruno does not teach the claimed glass composition with respect to the amount of metal oxides present.

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USPN 5,232,878 to Kasuga teaches that it is known in the art to add metal oxides such as  $\text{Na}_2\text{O}$ ,  $\text{K}_2\text{O}$ ,  $\text{MgO}$  and  $\text{CaO}$  in the proportions claimed by applicant to biocompatible glass compositions to yield a glass composition with excellent strength and biocompatibility. Kasuga discloses a glass composition with as little as 12%  $\text{SiO}_2$ ,  $\text{CaO}$  within the range of 10.1-23.4%,  $\text{MgO}$  within the range of 5.7-13.3%,  $\text{Na}_2\text{O}$  within the range of 8.3%-23.6%, and  $\text{K}_2\text{O}$  within the amount of 2.2-6.5% (col 4 line 35-col 5, line 11). Therefore it would have been obvious to one of ordinary skill in the art to modify the glass composition of Maruno with the proportions of metal oxides taught by Kasuga because of the strength and biocompatibility of the glass composition.

9. Claims 2-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maruno in view of Kasuga as applied to claim 1 above, and further in view of Maruno.

With respect to claim 2, Maruno further teaches the first layer to have a gradient concentration of HA particles such that there is a higher concentration of HA particles nearer the outer surface than the inner surface (col 5, lines 8-12).

With respect to claim 3, Maruno teaches the inclusion of a first intermediate layer located between the substrate and first layer, wherein said first intermediate layer comprises a glass composition as defined in claim 1 (col 5, lines 59-65).

With respect to claim 4, Maruno teaches the first layer to have a HA concentration of between 10 wt% and 40 wt% (col 8, lines 60-64).

With respect to claim 5, Maruno teaches the inclusion of a second intermediate layer located between the first intermediate layer and the substrate, all layers comprising the glass/HA composition of claim 1, wherein the first layer has the highest HA concentration, the second intermediate layer has the lowest HA concentration, and the first intermediate layer has an HA

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concentration between the amounts of the first layer and second intermediate layer (col 5, lines 33-54).

With respect to claim 6, absent a showing of unexpected results with an intermediate layer having exactly 20 wt% of HA and a first layer having exactly 40 wt% of HA, it is the examiner's position that the exact optimal percentage of HA present in the layers can be determined by routine experimentation within the previously claimed range of 0-50 wt% and thus is not deemed patentable.

With respect to claim 7, absent a showing of unexpected results with specific amounts of each of the claimed glasses, varying the composition of the glass within the bounds of claim 1 is merely a matter of routine experimentation and thus is not patentable.

With respect to claims 8-12, Maruno teaches the use of Ti or  $\text{Ti}_6\text{Al}_4\text{V}$  as a substrate. As stated above, Maruno in view of Kasuga teaches the claimed glass compositions. Absent a showing of unexpected results with specific glass compositions and HA concentrations, it is the examiner's position that both values are optimizable by routine experimentation and thus are not deemed patentable.

With respect to claims 13-20, Maruno, as stated above, teaches a multilayer article comprising a metal substrate of Ti or  $\text{Ti}_6\text{Al}_4\text{V}$ , n intermediate layers where n is 1 or 2, a first layer comprising an inner and outer surface, wherein said n intermediate layers are disposed between the metal substrate and the first layer and are each independently comprised of a glass/HA admixture, such that the first layer has a HA concentration greater than all layers under it and each n intermediate layer under the first layer has a HA concentration greater than the layer under it so as to establish a gradient of glass/HA admixtures. Maruno in view of Kasuga

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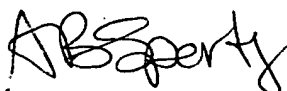
teaches the claimed glass compositions. Absent a showing of unexpected results with specific glass compositions and HA concentrations, both values are optimizable by routine experimentation and thus are not deemed patentable.

### *Conclusion*

The following patents are cited as containing relevant subject matter: USPN 5,665,121 to Gie et al and USPN 5,562,733 to Weissbach et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arden B. Sperty whose telephone number is 703-305-3143. The examiner can normally be reached on M-R, 08:00-16:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones can be reached on 703-308-3822. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.



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May 20, 2002

  
DEBORAH JONES

SUPERVISORY